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EXAMINER

PATEL, NIHIR B

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



## **DETAILED ACTION**

### ***Response to Arguments***

1. The objection to the abstract is withdrawn and the amendment to the abstract filed on June 30th, 2006 is acknowledged.

In reference to claims 40-45 being rejection under 35 U.S.C. § 112, first paragraph, the applicant recites that support for claims 40-45 may be found in the application as originally filed at, for example paragraphs [00101]-[00107] and [00132]-[00135]. After reviewing the applicant's specification, the specification recites "The mask has the characteristics of displaying the age via stress whitening" does not mention a user indicator. Therefore, claims 40-45 are still rejected rejection under 35 U.S.C. § 112, first paragraph.

The examiner would also like to point that a user indicator is not a structure but rather a material that transforms from transparent to frost/glassy. If the applicant argues that it is a structure it must be shown on the drawings.

In reference to claims 40-42, the applicant argues that the disclosure of Sprinkle does not contain or suggest that the rigid plastic material of the shell changes from optically transparent to a more glossy/frosty material after using the mask multiple times. The examiner disagrees with the applicant's argument. Col. 2 lines 44-50 of the Sprinkle reference teaches the shell being made of a rigid plastic material which is preferably optically transparent which will after using multiple times inherently change from optically transparent to a glossy/frosty indicating usage of the mask.

In reference to claim 46, the applicant argues that the disclosure of Gunaratnam contains or suggest that disassembly of the cushion clip 14 from the mask frame 11 will deform and/or

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break the connection between the cushion clip 14 and the mask frame. The examiner disagrees with the applicant's arguments. The removable of cushion clip will cause the cushion 13 to be disassembled which will inherently render the mask unusable because the cushion provides a tight seal with the user's face minimizing leakage and without the cushion there will be a maximum leakage making the mask unusable.

In reference to claim 58, the applicant argues that Dantanarayana does not disclose a valve member provided at the interface of an elbow in a frame. The examiner disagrees with the applicant's argument. Dantanarayana does disclose a valve member provided at the interface of an elbow in a frame (see figs. 43 and 44; paragraph [0136]).

### ***Response to Amendment***

2. The examiner acknowledges the amendment filed on August 3rd, 2010. The amendment comprises amending claims 40, 42, 43, 46 and 58; cancelling claims 1-39, 41 and 49-57; and adding new claims 69-71.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims **40-45** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims contains subject matter, specifically "a usage indicator" and "warning

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signal is in the form of one or more words" is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection is based on what the examiner regards as a usage indicator since the applicant has not provided any information in the specification.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims **40, 42 and 71** are rejected under 35 U.S.C. 102(e) as being anticipated by Sprinkle et al. (US 7,621,274).

7. **As to claim 40**, Sprinkle teaches an apparatus that comprises a frame **20 (see figs. 3 and 4; col. 2 lines 44-51)**, a cushion **40 (see figs. 3 and 4; col. 2 lines 55-62)**; and headgear **80 (see fig. 1; col. 4 lines 45-55)**, wherein at least one of the frame, cushion and the headgear includes a usage indicator to indicate a usage condition of the mask assembly wherein the usage indicator comprises at least a portion of the frame that is made of a material that exhibits stress whitening after repeated movement **(see col. 2 lines 44-50; the frame is made from transparent material and therefore it is inherent that after using the mask multiple times, the transparent material changes from transparent to a more glassy/frosty material indicating usage of the mask)**.

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8. As to **claim 42**, Sprinkle teaches an apparatus wherein the stress whitening takes the form of a warning signal **(the frame is made from transparent material and therefore after using the mask multiple times, the transparent material changes from transparent to a more glassy/frosty material indicates also indicates a warning signal)**.

9. As to **claim 71**, Sprinkle teaches an apparatus wherein an intensity of the stress whitening and/or an area of the frame that exhibits stress whitening increases after repeated movement **(the frame is made from transparent material and therefore after using the mask multiple times, the transparent material changes from transparent to a more glassy/frosty material after repeated movement indicates also indicates a warning signal)**.

*Claim Rejections - 35 USC § 102*

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claim **46** is rejected under 35 U.S.C. 102(e) as being anticipated by Gunaratnam et al. (US 7,185,652).

11. As to **claim 46**, Gunaratnam teaches an apparatus that comprises a frame **11** (see **fig. 3; col. 3 lines 50-55**); a cushion **13** provided to the frame **11** (see **fig. 3; col. 3 lines 50-55**); a cushion clip **14** provided to secure the cushion **13** between the cushion clip **14** and the frame **11** via a first connection (see **fig. 3**); and a swivel elbow **26** (see **fig. 1; col. 2 lines 28-35**) provided to the frame via a second connection, wherein at least one of the first and second connections is

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provided via a one-way snap which will deform and/or break upon attempt to disassemble to render the mask unusable.

12. Claims **58-61** are rejected under 35 U.S.C. 102(e) as being anticipated by Dantanarayana et al. (US 2004/0094157).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

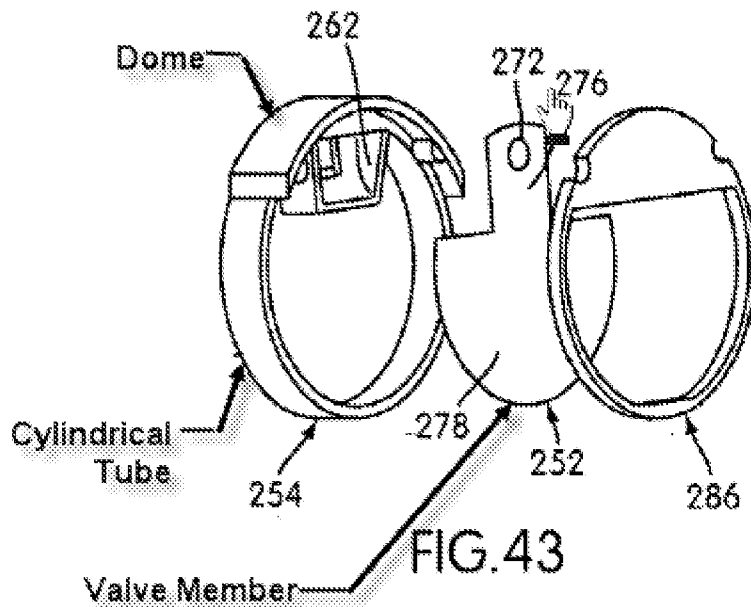
13. As to **claim 58**, Dantanarayana teaches an apparatus that comprises a frame **32** (see **fig. 4; paragraph [0071]**); an elbow (see **fig. 44**) provided to the frame and including an inlet conduit (see **fig. 44 below**) and a valve member **278** (see **fig. 43 below**) provided at an interface of the elbow in the frame, the valve member being configured to allow breathing of ambient air and to prevent back flow of gas towards the inlet conduit of the elbow in an unpressurized state (see **fig. 42; the figure shows arrows in both direction in the exhaust port indicating that it allows breathing of ambient air and the fact that the valve 278 is closed prevents back flow of gas towards in the inlet conduit**).

14. As to **claim 59**, Dantanarayana teaches an apparatus wherein the elbow includes an internal cylindrical tube **254** (see **fig. 43 below**) in communication with atmosphere and a dome (see **fig. 43 below**) that supports the tube, and wherein any back flow is guided through the tube and not the inlet conduit in the unpressurized state.

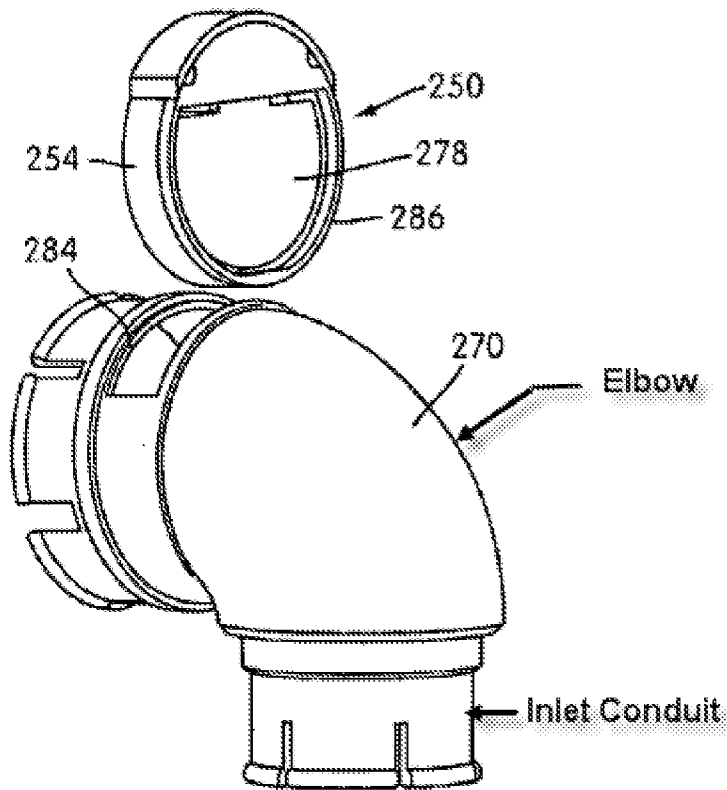
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15. As to **claim 60**, Dantanarayana teaches an apparatus wherein the elbow includes at least one inlet slot structured to allow ambient air to be channeled between the valve member and the frame for supply to the patient, when operating in the unpressurized state (**see fig. 42; the figure shows arrows in both direction in the exhaust port indicating that that it allows breathing of ambient air and the fact that the valve 278 is closed prevents back flow of gas towards in the inlet conduit**).

16. As to **claim 61**, Dantanarayana teaches an apparatus wherein the valve member is structured to separate from the tube during operation in a pressurized state, to thereby allow pressurized gas to enter an aperture of the frame (**fig. 40 shows that the valve member is separated from the tube 254 during operation in a pressurized state, allowing gas to enter an aperture of the frame**).







***Claim Rejections - 35 USC § 103***

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

19. Claim **68** is rejected under 35 U.S.C. 103(a) as being unpatentable over Sprinkle et al. (US 7,621,274).

20. **As to claim 68**, Sprinkle substantially discloses the claimed invention; see rejection of claim 40 above, but does disclose a frame that is made from materials like polypropylene, polyethylene or PETE. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Sprinkle's invention by providing a frame that is made from materials like polypropylene, polyethylene or PETE so that it is strong enough to bend or flex just enough to form the contours of the user's face in order to minimize the leakage, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, **125 USPQ 416**.

*Allowable Subject Matter*

22. Claims **43-45, 47, 48, 62-67, 69 and 70** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not disclose a first connection that includes a rod provided to the cushion clip which passes through at least one of the cushion and the frame, wherein the rod includes an enlarged head portion which allows assembly of the cushion clip to the frame, but substantially prevents removal of the cushion clip from the frame; the valve member creating an audible indicator during operation in a pressurized

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sate; and the elbow includes a central tube portion and an inner tube suspended from a dome portion of the elbow.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIHIR PATEL whose telephone number is (571)272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nihir Patel/  
Examiner, Art Unit 3772

/Patricia Bianco/

Supervisory Patent Examiner, Art Unit 3772